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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,690	06/26/2007	Tatsuhiko Kodama	14875-167US1 C1-A0326P-US	9489

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EXAMINER	
WILSON, MICHAEL C	

ART UNIT	PAPER NUMBER
1632	

NOTIFICATION DATE	DELIVERY MODE
08/05/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary	Application No.	Applicant(s)	
	10/594,690	KODAMA ET AL.	
	Examiner	Art Unit	
	Michael C. Wilson	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 July 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 16-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 16-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7-6-10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7-2-10 has been entered.

Claims 2-15 have been canceled. Claims 1 and 16-18 remain pending and under consideration.

The title has been changed to more closely reflect the claimed invention.

Applicant's arguments filed 7-2-10 have been fully considered but they are not persuasive.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

When referring to the specification, please use page and line number of the original specification. Do not simply use the paragraph number – the original specification does not have paragraph numbers.

Claim Rejections - 35 USC § 112

Claims 16-18 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for producing an antibody against a membrane protein comprising:

(a) immunizing the transgenic mouse of claim 1 with a baculoviral particle, wherein the baculoviral particle comprises a nucleic acid sequence encoding a membrane protein, and wherein the membrane protein is displayed on the surface of the baculoviral particle;

(b) recovering an antibody from the transgenic mouse, wherein the antibody recognizes the membrane protein, does not reasonably provide enablement for immunizing the transgenic mouse with an immunogen comprising i) a baculoviral particle or portion thereof, and ii) a target antigen as broadly claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Support for "membrane protein" is in original claim 14. Support for displaying the membrane protein on the surface of the baculoviral particle can be found on pg 10, lines 12-15 and 21-24.

Claim 1 is directed toward a transgenic mouse whose genome comprises a nucleic acid sequence encoding baculovirus gp64, wherein the gp64 is soluble and lacks a transmembrane region and wherein the mouse is fertile. Claim 16 is drawn to a method making antibodies by i) immunizing the transgenic mouse of claim 1 with an immunogen comprising baculovirus particle or portion thereof and a target antigen, and ii) obtaining an antibody against the target antigen.

The specification teaches making transgenic mice expressing the extracellular, soluble region of baculovirus gp64 (SEQ ID NO: 3) (pg 16, lines 18-20; pg 17, lines 14-

33). The specification states mice were immunized with a budding baculovirus (pepT1-AcMNPV (pepT1-VB)) (sentence bridging pg 19-20), and then states mice were given 1 mg/animal (pg 20, lines 2-7). The specification states mice expressing soluble gp64 induced tolerance (pg 20, lines 17-19; Fig. 3). However, the specification does not clearly set forth the structure of what was administered to the mice. Baculovirus is not administered at 1 mg/animal, for example (pg 20, line 7); viral doses are measured in particle numbers or infectious units, not milligrams. The structure of pepT1-AcMNPV used to immunize the mice is wholly unclear. Furthermore, applicants do not teach obtaining antibodies against pepT1 or provide adequate guidance that antibodies against pepT1 actually occur.

Since the time of filing, Saitoh (J. Immunological Methods, 2007, Vol. 332, pg 104-117) taught sgp64 transgenic mice were immunized with PepT1 expressed on the surface of baculoviral particles and obtained antibodies against pepT1. Saitoh is considered post-filing evidence for obtaining antibodies against pepT1.

The specification fails to enable those of skill in the art at the time of filing to immunize the transgenic mouse with any "immunogen" comprising i) a baculovirus or portion thereof and ii) a target antigen as broadly claimed. The specification fails to teach how to introduce the target antigen in context of a portion of a baculovirus. The specification fails to teach how to immunize without the target antigen being expressed on the surface of the baculovirus particles. The specification fails to teach how to introduce the target antigen expressed inside the baculoviral particle and not with the envelope proteins on the surface of the particle. If the target antigen is not expressed

on the surface of the baculovirus, then using the transgenic of claim 1 is moot because the method can be performed with a wild-type mouse because the antigen will not contact the immune system. If the target antigen is expressed inside the baculoviral particle but not displayed on the surface, the antigen would not induce an antibody response because the humoral immune system (for antibody production) would not have access to a target antigen. The specification fails to teach how to immunize with a baculoviral particle expressing a non-membrane protein. Thus, it would have required those of skill undue experimentation to determine how to obtain antibodies against the target antigen. Given the lack of teachings in the specification taken with the post-filing evidence, the claims should be limited to

While the membrane protein encompasses gp64 baculovirus antigen, which is not a useful target antigen in the method claimed because the specification states the mice are tolerized to gp64, this is considered a non-operative embodiment.

Applicants argue those of skill could perform the method using portions of baculovirus as claimed. Applicants' argument is not persuasive. The argument is unfounded in any science, any teachings in the specification, or any art at the time of filing. It cannot be envisioned how to perform the method using a portion of a baculovirus as claimed.

Applicants argue those of skill could perform the method by expressing the target antigen any wherein in the baculovirus. Applicants' argument is not persuasive. The argument is unfounded in any science, any teachings in the specification, or any art at the time of filing. If the target antigen is not expressed on the surface of the

baculovirus, then using the transgenic of claim 1 is moot because the method can be performed with a wild-type mouse because the antigen will not contact the immune system. If the target antigen is expressed inside the baculoviral particle but not displayed on the surface, the antigen would not induce an antibody response because the humoral immune system (for antibody production) would not have access to a target antigen.

Applicants arguments fail to address how to perform the method using any target antigen other than a membrane protein.

Double Patenting

Claims 16-18 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 2 of US Patent 7,750,204 (Application No. 10/516603). Although the conflicting claims are not identical, they are not patentably distinct from each other because the both require making antibodies against a target antigen using a transgenic mouse expressing gp64 that is immunotolerant to gp64 using a "baculovirus or portion thereof" ('690) or a "budding virus or portion thereof" ('204). The species of "baculovirus or portion thereof" ('690) is an obvious variant of a "budding virus or portion thereof" ('204). The "pepT1" expressed by the budding virus or portion thereof in '024 is an obvious variant of the "target antigen" expressed by the baculovirus of '690. Otherwise, the claims have different wording that does not patentably distinct the claims of '204 from those of '690. Accordingly, the claims are not patentably distinct because the different species/genus within the claims are obvious variants and could have been claimed in either

application. Issuing a new patent term in the instant application would unjustly extend the patent term for one invention. The claims in each are not patentably distinct.

Applicants argue the limitations are different in each set of claims. Applicants' arguments are not persuasive. The limitations are obvious in view of the disclosure of each application. The claims in '204 could have been claimed in the instant application, and the claims in the instant application could have been claimed in '204. The two-way obviousness test is met; accordingly, the rejection is valid and has been maintained.

Conclusion

No claim is allowed.

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached at the office on Monday through Friday from 9:30 am to 6:00 pm at 571-272-0738.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on 571-272-4517.

The official fax number for this Group is (571) 273-8300.

Michael C. Wilson

/Michael C. Wilson/
Primary Patent Examiner